

**IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA**

**JANE E. REAM and  
WILLIAM J. REAM, SR.  
Plaintiffs**

**v.**

**ETHICON, INC. and  
JOHNSON & JOHNSON,  
Defendants**

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**No. 1:20-cv-00922**

**(Judge Kane)**

**MEMORANDUM**

Presently before the Court is the supplemental motion for summary judgment (Doc. No. 60) filed by Defendants Ethicon, Inc. (“Ethicon”) and Johnson & Johnson (“Johnson & Johnson”) (collectively, “Defendants”). For the reasons stated below, the Court will grant Defendants’ motion.

**I. BACKGROUND**

**A. Factual Background<sup>1</sup>**

This is a product-liability action which originated out of a multidistrict litigation in the United States District Court for the Southern District of West Virginia (the “MDL court”). Plaintiffs Jane Ream (“Mrs. Ream”) and William Ream (“Mr. Ream”) (collectively, “Plaintiffs”) sued Defendants on December 17, 2013 to recover damages for injuries sustained by Mrs. Ream as a result of alleged defects in a transvaginal polypropylene mesh product (“TVT”) marketed and manufactured by Defendants. Defendants’ TVT was surgically implanted into Mrs. Ream

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<sup>1</sup> The Court draws the following facts from Defendant’s statement of material facts (Doc. No. 62), except as otherwise noted. The facts, unless otherwise noted by the Court, are undisputed.

on February 1, 2011 to treat a medical condition known as a cystocele<sup>2</sup> as well as Mrs. Ream's frequent urination and stress urinary incontinence.<sup>3</sup> (Doc. No. 62 ¶ 3.)

Mrs. Ream was deposed on September 27, 2018. (See Doc. No. 62-3 at 2.) During her deposition, Mrs. Ream testified that after the surgeon inserted the TVT, she experienced issues with increased urinary urgency and incontinence. (Doc. No. 62 ¶¶ 4, 5.) Mrs. Ream also testified that she began experiencing dyspareunia—that is, pain during sexual intercourse—“a couple [of] months” after the TVT was implanted. (Id. ¶ 6.) Mrs. Ream testified that both she and Mr. Ream could feel the “rough, jaggedy edges” of the TVT during intercourse. (Id. ¶¶ 7, 8.) Further, Mrs. Ream testified that she experiences pelvic and abdominal pain when “getting in and out of a car,” “walking too much,” using the restroom, bending over, lifting things, or walking up or down the stairs. (Doc. No. 62-3 at 9-10.) These injuries have allegedly caused Mrs. Ream emotional and psychological distress. (Id. at 16.)

In her sworn Plaintiff Fact Sheet (Doc. No. 62-1), Mrs. Ream stated that the first time she experienced any of these injuries was “[i]n the immediate aftermath” of the surgery; “[t]hree weeks after the implant,” Mrs. Ream stated, “[I] started having severe lower abdominal pain.” (Doc. No. 62-1 at 8.) At her deposition, however, Mrs. Ream testified differently:

Q: Now, you had your implant on February 1st, 2011. Is that correct?

A: Yes.

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<sup>2</sup> A cystocele, also known as an anterior prolapse, is a condition that occurs in women when the bladder drops from its normal position in the pelvis and pushes on the walls of the vagina. See Kennedy v. Ethicon, Inc., No. 5:20-CV-0185, 2020 WL 4050459, at \*1 n.1 (E.D. Pa. Jul. 20, 2020).

<sup>3</sup> Stress urinary incontinence is a chronic condition that causes urine to leak involuntarily during everyday activities such as exercise, laughing, sneezing, and coughing. See Carlino v. Ethicon, Inc., 208 A.3d 92, 99 (Pa. Super. Ct. 2019).

Q: And now following the implant, when's the first time you ever experienced symptoms of any type of—of any of the injuries we've discussed that indicated to you something was wrong?

...

A: Several months after, perhaps. Five, six months maybe.

Q: And what were you experiencing at that time?

A: I still was experiencing the pain, the stretching, pulling, tightness, pressure.

Q: Anything else at that time?

A: Not that I recall.

Q: And did you talk to a doctor about these symptoms?

A: Not until I went back to see Dr. Robinson a year and a half after she performed the surgery.

(Doc. No. 62-3 at 17 (emphasis added).) Mrs. Ream also testified that she conducted independent internet research to ascertain whether the TVT was the cause of her injuries:

Q: [Have you] done any other research about any of the subject matter of this litigation?

A: After and when I started having the pulling, stretching, pain, discomfort, I probably tried to research online to see if the sling would have been causing me to have this discomfort and pain and the interference with even, like, intimacy.

Q: And do you remember anything you saw on the internet relating to that?

A: Yes. It mentioned the problems that I was having.

Q: Do you have any recollection as to how long after your 2011 implant you did this research?

A: Probably a couple months after.

(Id. at 8 (emphasis added).) Despite this research, Mrs. Ream claims that the first time she attributed her symptoms to the TVT was when she and her husband “saw [TV] ads regarding the [multidistrict] mesh litigation in approximately February 2013.” (Doc. No. 62-1 at 8.)

Plaintiffs hired a case-specific expert witness, Dr. John P. Brennan, M.D. (“Dr. Brennan”), to opine on the nature and cause of Mrs. Ream’s injuries. (See Doc. No. 62-6 at 2.) Dr. Brennan prepared a two-page expert report dated August 25, 2018. (Id.) In this report, Dr. Brennan lists the following complications suffered by Mrs. Ream: dysuria, bladder spasms, pelvic pain, abdominal pain, dyspareunia, abdominal pain, pelvic pain, urinary incontinence, bladder infections, and painful sexual intercourse. (Id. at 2-3.) He concludes that Mrs. Ream’s complications are the “result of her pelvic mesh implant[.]” (Id. at 2.) Dr. Brennan further concludes that “the benefits of the mesh are outweighed by the severe, debilitating[,] and life[-]changing complications associated with the device”; that the mesh “lacked adequate warnings to physicians about all of these risks”; and that “feasible, safer alternatives to this device [exist] for patients.” (Id. at 3.) In sum, he concludes as follows:

I have considered her pre-implant medical and surgical history, and utilized my education, experience, and training in performing a differential diagnosis to rule out any potential causes of Jane Ream’s pelvic injuries. To a reasonable degree of medical certainty, the defective mesh implanted in Jane Ream in February, 2011 was the cause of her multiple symptoms and complications.

(Id.)

## **B. Procedural Background**

Plaintiffs filed suit in the MDL court on December 17, 2013. (Doc. No. 1.) They asserted claims of negligence (Count I); strict liability, under manufacturing-defect, design-defect, and failure-to-warn theories (Counts II-V, respectively); common-law fraud (Count VI); fraudulent concealment (Count VII); constructive fraud (Count VIII); negligent misrepresentation (Count IX); negligent infliction of emotional distress (Count X); breach of express and implied warranties (Counts XI and XII, respectively); violation of consumer protection laws (Count XIII); gross negligence (Count XIV); unjust enrichment (Count XV); loss

of consortium (Count XVI); punitive damages (Count XVII); and tolling of the statute of limitations pursuant to the discovery rule (Count XVIII).

While presiding over the MDL, Judge Joseph R. Goodwin issued several case-management orders, including one setting a December 3, 2018 deadline for the filing of dispositive motions. (Doc. No. 10.) Defendants timely filed a motion for summary judgment in the MDL court (Doc. No. 23), and that motion remained pending when, on June 8, 2020, the MDL court transferred Plaintiffs' case to this Court. (See Doc. No. 45.) This Court held a status conference with the parties on July 15, 2020, at which Defendants' counsel indicated his desire to file a motion for leave to file a supplemental summary judgment motion. (Doc. No. 59 at 1.) Defendants filed that motion for leave, and the Court granted Defendants' request to file the instant supplemental summary judgment motion. (Doc. No. 59 at 4.)<sup>4</sup> Defendants then filed the instant motion on October 2, 2020. (See Doc. No. 60.) The motion has been fully briefed (Doc. Nos. 61, 70, 72) and is therefore ripe for disposition.

## **II. LEGAL STANDARD**

Federal Rule of Civil Procedure 56(a) requires the Court to render summary judgment "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." See Fed. R. Civ. P. 56(a). "[T]his standard provides that the mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no genuine issue of material fact." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48 (1986).

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<sup>4</sup> The Court's Order granting Defendants' motion for leave to file a supplemental motion for summary judgment denied Defendants' original motion for summary judgment as moot. (Doc. No. 59.)

A disputed fact is “material” if proof of its existence or nonexistence would affect the outcome of the case under applicable substantive law. See id. at 248; Gray v. York Newspapers, Inc., 957 F.2d 1070, 1078 (3d Cir. 1992). An issue of material fact is “genuine” if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. See Anderson, 477 U.S. at 287-88.

When determining whether there is a genuine issue of material fact, the Court must view the facts and all reasonable inferences in favor of the nonmoving party. See, e.g., Moore v. Tartler, 986 F.2d 682 (3d Cir. 1993); Clement v. Consol. Rail Corp., 963 F.2d 599, 600 (3d Cir. 1992); White v. Westinghouse Elec. Co., 862 F.2d 56, 59 (3d Cir. 1988). In order to avoid summary judgment, however, the nonmoving party may not rest on the unsubstantiated allegations of his or her pleadings. When the party seeking summary judgment satisfies its burden under Rule 56 of identifying evidence that demonstrates the absence of a genuine issue of material fact, the nonmoving party is required to go beyond his pleadings with affidavits, depositions, answers to interrogatories, or the like in order to demonstrate specific material facts that give rise to a genuine issue. See Celotex Corp. v. Catrett, 477 U.S. 317, 324 (1986). The party opposing the motion “must do more than simply show that there is some metaphysical doubt as to the material facts.” See Matsushita Elec. Indus. Co. v. Zenith Radio, 475 U.S. 574, 586 (1986). When Rule 56 shifts the burden of production to the nonmoving party, that party must produce evidence to show the existence of every element essential to its case that it bears the burden of proving at trial, for “a complete failure of proof concerning an essential element of the nonmoving party’s case necessarily renders all other facts immaterial.” See Celotex, 477 U.S. at 323; see also Harter v. G.A.F. Corp., 967 F.2d 846, 851 (3d Cir. 1992).

### III. DISCUSSION

As an initial matter, the Court notes that Plaintiffs abandoned Counts II, IV, and VI-XV, as well as their negligent and strict liability failure to warn claims (Count III), in connection with the briefing of the instant motion and Defendants' initial motion for summary judgment. (See Doc. No. 61 at 1-2; Doc. No. 70-2 at 3; Doc. No. 71 ¶ 18.) Because the parties agree that Defendants are entitled to judgment as a matter of law on these claims, the Court will grant summary judgment as to these claims. Accordingly, the only claims remaining before this Court are: Plaintiffs' negligence – design defect claim (Count I), Plaintiffs' strict liability – design defect claim (Count V), and Plaintiffs' claim for loss of consortium (Count XVI).<sup>5</sup>

With regard to those remaining claims, Defendants make three principal arguments in favor of summary judgment: (1) that Plaintiffs' claims are barred by the statute of limitations; (2) that Plaintiffs' strict-liability claim is not cognizable under Pennsylvania law; and (3) that Plaintiffs have failed to establish a sufficient causal link between Mrs. Ream's injuries and a particular defect in the TVT. The Court finds it unnecessary to address arguments (1) and (2) because, as explained more fully infra, it concludes that, even assuming that factual issues would preclude a resolution of the statute of limitations issue on summary judgment, and assuming that Pennsylvania law permits Plaintiffs to assert a strict liability – design defect claim, Defendants are still entitled to judgment as a matter of law because Plaintiffs have failed to offer sufficient evidence of causation with regard to their negligence and strict liability design defect claims.

#### A. Legal Standard

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<sup>5</sup> With respect to Count XVIII, Pennsylvania law conceives of the discovery rule as a common law doctrine affecting the tolling of the applicable statute of limitations, not as a discrete cause of action. See Dubose v. Quinlan, 173 A.3d 634, 638 n.4 (Pa. 2017). With respect to Count XVII, punitive damages are a remedy, not a separate cause of action. See 22 Am. Jur. Damages § 567.

Pursuant to Pennsylvania law, “[p]roof of causation is a necessary element in a products liability action. Absent a causal relationship between the defendant’s product and the plaintiff’s injury the defendant cannot be held liable on a theory of negligence, strict product liability, or misrepresentation. . . . to meet her causation burden, plaintiff must first establish that [the product] is capable of causing [the alleged injury] (general causation). She must then establish that, in her particular case, [the product] did in fact cause her [alleged injury] (specific causation).” See Soldo v. Sandoz Pharm. Corp., 244 F. Supp. 2d 434, 524-25 (W.D. Pa. 2003) (citing Heller v. Shaw Indus., No. 95-7657, 1997 WL 535163, at \*6 (E.D. Pa. 1997), aff’d, 167 F.3d 146 (3d Cir. 1999)). Further, a plaintiff must establish causation through admissible expert testimony. See Soldo, 244 F. Supp.2d at 525 (explaining, in case involving alleged personal injuries from a prescription drug, that “[i]n a case such a this one involving complex issues of causation not readily apparent to the finder of fact, plaintiff must present admissible expert testimony to carry her burden. If her expert testimony cannot support both general and specific causation, summary judgment for the defendant must be granted”) (citing Heller, 167 F.3d at 153). A plaintiff’s expert opinions must be expressed to a reasonable degree of medical certainty, because opinions expressing only “possibilities” do not suffice to support admissibility. See id. at 525-26 (collecting cases).

## **B. Arguments of the Parties**

Defendants note that Plaintiffs have designated one case-specific expert, Dr. Brennan, to establish specific causation. (Doc. No. 61 at 13.) Defendants argue that the report produced by Dr. Brennan fails to satisfy Plaintiffs’ summary judgment burden, as it is only two (2) pages long and, after reciting several facts, concludes simply that “[t]o a reasonable degree of medical certainty, the defective mesh implanted in Jane Ream in February, 2011 was the cause of her



multiple symptoms and complications.” (Id.) (quoting Doc. No. 62-6 at 3). Defendants maintain that this report fails to establish that a specific defect in the TVT caused Mrs. Ream’s injuries by failing to “even identify the ‘defect’ in the first instance” and then “even attempt[ing] to connect any alleged, unspecified defects in the TVT as the cause of any of Mrs. Ream’s claimed injuries.” (Id.)

In response, Plaintiffs maintain that “the opinions of Dr. Brennan cannot be considered in a vacuum and are to be considered alongside Plaintiffs’ liability and general experts. Plaintiffs produced general expert reports setting forth the defects in the TVT. Plaintiffs’ general experts describe how the physical characteristics of the TVT rendered the product defective.” (Doc. No. 70-2 at 14.) For example, Plaintiffs point to the expert report of Dr. Uwe Klinge, which they maintain “describes the manner in which TVT’s polypropylene mesh causes an inflammatory response process known as foreign body reaction that led to a fibrotic reaction, scarring, contraction or shrinkage of the mesh and surrounding tissue, and ultimately pain and erosions.” (Id.) Plaintiffs maintain that “[t]he types of injuries and complications” discussed that are “associated with defects of the TVT” “are exactly the types of injuries of which Mrs. Ream suffered.” (Id.)

### **C. Whether Summary Judgment is Warranted**

Upon careful review of the parties’ arguments, the relevant authorities, and the record, viewed in the light most favorable to Plaintiffs, the nonmoving parties, the Court concludes that Plaintiffs have failed to produce sufficient evidence from which a factfinder could reasonably conclude that Plaintiffs met their burden to establish design defect causation with regard to Plaintiffs’ alleged injuries. As an initial matter, the Court agrees with Defendants that Plaintiffs “implicitly concede that Dr. Brennan failed to establish design defect causation, through their

recent Motion to Supplement Dr. Brennan’s expert report, filed after Defendants brought this motion,” which seeks to “supplement the contents of Dr. Brennan’s inadequate report with new opinions based on information that existed before the time his report was served.” (Doc. No. 72 at 8.) In that motion, Plaintiffs argued that they should be permitted to supplement Dr. Brennan’s report to “provide Dr. Brennan’s opinions concerning which of [the device’s] many defects was the cause of Mrs. Ream’s injuries.” (Doc. No. 58 at 3.) The Court recently issued an Order denying Plaintiffs’ motion to supplement Dr. Brennan’s expert report as an impermissible attempt to utilize Federal Rule of Civil Procedure 26(e) to strengthen Dr. Brennan’s opinion so as to withstand the instant motion for summary judgment. (Doc. No. 73.)

Further, with regard to Plaintiffs’ argument that the sufficiency of Dr. Brennan’s report should be viewed in conjunction with Plaintiffs’ general expert reports describing defects in the TVT, the Court notes that another district court recently found that a report by Dr. Brennan, nearly identical to the one filed in this case, was insufficient to support causation in a design defect case, even where coupled with a general causation report. In Abt v. Ethicon, No. 1:20-cv-00047-SRC, 2020 WL 4887022 (E.D. Mo. Aug. 20, 2020), the Court stated that:

Nowhere in Dr. Brennan’s report does he connect a design defect with Abt’s injuries. He conclusorily states that generally the defective device caused Abt’s injuries. He provided no specifics such as what design defect caused what injuries, or how any design defect caused Abt’s injuries. He essentially concludes that the mere presence of the TVT-O caused Abt’s injuries.

See id. at \*3. The Court continued: “[c]onsidering Dr. Rosenzweig’s [general expert] report with Dr. Brennan’s report, at most Abt has established correlation between the implant’s design defects and her injuries; she has not shown causation.” See id. at \*4. Accordingly, the Court held that “[w]ithout some evidence showing her implant caused her injuries, beyond conclusory statements, Abt’s claim for strict liability design defect fails.” See id.; Lampron v. Johnson &

Johnson and Ethicon, Inc., No. 20-cv-317-JD, 2020 WL 3452150, at \*4 (D.N.H. June 24, 2020) (also rejecting Plaintiffs’ efforts to utilize the opinions of a case-specific expert and a general causation expert to show that Plaintiffs’ injuries were caused by Ethicon’s device); see also Lynch v. Ethicon, Inc., LLC and Johnson & Johnson, No. 2:20-cv-00217-SMJ, 2020 WL 5733184, at \*2 (E.D. Wash. Sept. 24, 2020) (stating that “Lynch’s experts have not opined that a design defect in Defendants’ Mesh Products caused her injuries. . . . without an expert opinion asserting a causal link between the general design defects identified by Dr. Veronikis and Lynch’s injuries, Lynch has not established a genuine issue of material fact”); Nix v. Ethicon, Inc. and Johnson & Johnson, No. 1:19-cv-04896-SCJ, 2020 WL 5525172, at \*3-4 (N.D. Ga. Sept. 14, 2020) (holding that “expert testimony is necessary to demonstrate not just that TVT-O, a complex medical device, had alleged design defects that could have caused Ms. Nix’s injuries, but also how one or more of those alleged defects actually caused her injuries. . . . Plaintiff’s sole expert, Dr. Daucher, offers no analysis of the design of TVT-O or any opinion on what alleged defect caused Ms. Nix’s injuries”).<sup>6</sup> The expert report authored by Dr. Brennan here simply fails to identify a defect in the TVT and explicitly link that defect to the injuries allegedly suffered by Mrs. Ream; therefore it fails to provide sufficient evidence from which a reasonable factfinder could conclude that a defect in Defendants’ TVT proximately caused Mrs. Ream’s alleged injuries. Accordingly, the Court finds that Defendants are entitled to summary judgment on Plaintiffs’ negligence and strict liability design defect claims.

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<sup>6</sup> The Court finds Plaintiffs’ citation to Thompson, et al. v. Ethicon, Inc., et al., No. SAG-19-03159, 2020 WL 3893253 (D. Md. July 10, 2020) in support of their argument that Dr. Brennan’s expert report suffices to establish causation for purposes of opposing summary judgment to be unavailing. Thompson is distinguishable from the instant case, because in that case, the specific causation expert “identified a design defect – mesh erosion, which is one of the defects noted by the general expert witnesses – and tied that to [the plaintiff’s] ‘current complaints.’” See id. at \*6.

Further, as Defendants note, because Plaintiffs have failed to create a genuine issue of material fact as to Plaintiffs' design defect claims, Plaintiffs' loss of consortium claim fails as well. This is so because "[a]ny action for loss of consortium is derivative, depending for its viability upon the substantive merit of the injured party's claims." See Schroeder v. Ear, Nose and Throat Assocs. of Lehigh Valley, Inc., 557 A.2d 21, 22 (Pa. Super. 1989) (citing Boarts v. McCord, 511 A.2d 204 (Pa. Super. 1986)); Sutcliffe v. Bernese, No. 4:19-cv-00317, 2019 WL 3776560, at \*3 (M.D. Pa. Aug. 12, 2019) (same).

#### **IV. CONCLUSION**

For all of the foregoing reasons, the Court will grant Defendants' supplemental motion for summary judgment in its entirety. An appropriate Order follows.